UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re FENOFIBRATE PATENT LITIGATION	:	ECF Case No. 1:11-md-02241 (JSR)

JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT

Pursuant to the schedule established during the joint conference call with the Court on June 1, 2011, Plaintiff Lupin Atlantis Holdings S.A. ("LAH"), Plaintiff/Defendant Ethypharm S.A. ("Ethypharm"), and Defendants Paddock Laboratories, Inc., Cerovene, Inc., Mylan Inc., Mylan Pharmaceuticals, Inc., Ranbaxy Laboratories Limited, Ranbaxy Inc., Ranbaxy Pharmaceuticals, Inc., Apotex, Inc. and Apotex Corp. (collectively "Defendants"), by and through their attorneys, hereby set forth, in Exhibit A, each claim term, phrase, or clause in U.S. Patent No. 7,101,574 ("the '574 patent") and U.S. Patent No. 7,863,331 ("the '331 patent") that such party contends requires construction by the Court and each party's proposed construction of said claim terms, as well as definitions of claim terms on which the parties have reached agreement.

The parties agree that there will not be a need to present any expert testimony at the claim construction hearing set for August 1, 2011.

The '574 patent has 34 claims, two of which are independent claims, claims 1 and 19. The remaining dependent claims add additional limitations to those independent claims. The two independent claims are set forth below with the terms or phrases requested to be construed underlined:

1. A pharmaceutical composition in the form of granules, wherein each granule comprises a neutral microgranule on which is a composition comprising: micronized fenofibrate, a surfactant, and a binding cellulose derivative as a solubilization adjuvant, and

wherein said fenofibrate is present in an amount greater than or equal to 60% by weight, relative to the weight of said pharmaceutical composition, and further wherein said binding cellulose derivative represents between 2 to 15% by weight, relative to the weight of said pharmaceutical composition.

19. A pharmaceutical composition in the form of granules, wherein each granule comprises a neutral microgranule on which is a composition comprising: micronized fenofibrate, a surfactant, and a binding cellulose derivative as a solubilization agent, wherein the mass ratio of said fenofibrate to said binding cellulose derivative is between 5/1 and 15/1.

The '331 patent has 4 claims, of which claim 1 is the sole independent claim. The remaining dependent claims add additional limitations to claim 1. Claim 1 is set forth below with the terms or phrases requested to be construed underlined:

1. A method of reducing food effect when treating hypertriglyceridemias and/or hypercholesterolemias and/or hyperlipidemias in a patient in need thereof comprising administering to said patient a therapeutically effective amount of a pharmaceutical composition comprising micronized fenofibrate, a surfactant and hydroxypropylmethylcellulose, wherein said composition is in the form of granules comprising:

(a) a neutral core; and

(b) an active layer, surrounding the neutral core;

wherein said neutral core comprises a sugar or a sugar mixed with starch; said active layer comprises the micronized fenofibrate, the surfactant, and the binding cellulose derivative; and wherein the mass ratio of said fenofibrate to said hydroxypropylmethylcellulose is between 5/1 and 15/1, and said hydroxypropylmethylcellulose represents between 5 and 12% by weight of the composition.

EXHIBIT A

Claim Terms of The '574 Patent To Be Construed By The Court

Claim Term	LAH's/Ethypharm's Proposed Construction	Defendants' Proposed Construction
pharmaceutical composition	LAH and Ethypharm do not believe that any construction is required; however, if deemed necessary, LAH and Ethypharm propose the following: a composition which is suitable for pharmaceutical use	all of the active and inactive ingredients in the final dosage form
said pharmaceutical composition	LAH and Ethypharm do not believe that any additional construction is required; however, if deemed necessary, LAH and Ethypharm propose the following: the pharmaceutical composition in the form of granules, wherein each granule comprises a neutral microgranule on which is a composition comprising: micronized fenofibrate, a surfactant, and a binding cellulose derivative as a solubilization adjuvant/agent* *the underlined disputed terms are understood to incorporate LAH's/Ethypharm's proposed constructions as outlined below	all of the active and inactive ingredients in the final dosage form

granules	Neutral microgranules on which there is a mixture of micronized fenofibrate, a surfactant, and a binding cellulose derivative as a solubilization adjuvant/agent	many discrete granules
granule	Neutral microgranule on which there is a mixture of micronized fenofibrate, a surfactant, and a binding cellulose derivative as a solubilization adjuvant/agent	neutral microgranule on which is sprayed a suspension of micronized fenofibrate, a surfactant, and a binding cellulose derivative as a solubilization adjuvant/agent
each granule	No additional construction necessary	each and every granule in the pharmaceutical composition contains all the required ingredients
neutral microgranule	A therapeutically neutral substrate or region of a substrate	sugar or sugar mixed with starch particle having a size of between 200 and 1,000 microns and containing no fenofibrate
surfactant	A substance that lowers the surface tension of water	**One or more defendants propose the following construction:** a water-soluble substance, that when present in a sufficient amount and under appropriate conditions, increases the bioavailability of fenofibrate, and does not include anti-foaming agents such as simethicone **One or more defendants propose the following construction:** a water-dispersible amphiphilic organic compound that when present in a sufficient amount and under appropriate conditions, reduces the surface tension of water, and does not include anti-foaming agents such as simethicone

binding cellulose derivative as a solubilization adjuvant/agent	A cellulose-based polymer in said pharmaceutical composition that binds the micronized fenofibrate to the neutral microgranule and increases the micronized fenofibrate's solubility and/or rate of solubilization	any and all water-soluble cellulose-based polymer, such as HPMC, in the pharmaceutical composition that is capable of binding micronized fenofibrate to the neutral microgranule and increasing the micronized fenofibrate's solubility or rate of solubilization
micronized fenofibrate	Fenofibrate that has a smaller particle size than non-micronized fenofibrate such that it exhibits enhanced solubility and/or rate of solubilization when compared to non-micronized fenofibrate	fenofibrate particles of a size less than 15 microns free of other ingredients when micronized, and present in an aqueous suspension with one or more other ingredients when coated on the neutral core or neutral microgranule
wherein said fenofibrate is present in an amount greater than or equal to 60% by weight, relative to the weight of said pharmaceutical composition	weight of said micronized fenofibrate in said pharmaceutical composition divided by the weight of said pharmaceutical composition times 100 must be greater than or equal to 60[1]	weight of all of the micronized fenofibrate in the pharmaceutical composition divided by the weight of the pharmaceutical composition times 100 must be greater than or equal to 60
wherein said binding cellulose derivative represents between 2 to 15% by weight, relative to the weight of said pharmaceutical composition	weight of said binding cellulose derivative as a solubilization adjuvant/agent in said pharmaceutical composition divided by the weight of said pharmaceutical composition times 100 is between 2 to 15[2]	weight of all of the binding cellulose derivative in the pharmaceutical composition divided by the weight of the pharmaceutical composition times 100 is between 2 to 15

[1] Lupin Atlantis and Ethypharm propose this definition with the understanding that it inherently incorporates their proposed construction of the terms "micronized fenofibrate" and "said pharmaceutical composition."

[2] Lupin Atlantis and Ethypharm propose this definition with the understanding that it inherently incorporates their proposed construction of the claim terms "binding cellulose derivative as a solubilization adjuvant/agent" and "said pharmaceutical composition."

wherein the mass ratio of said fenofibrate to said binding cellulose derivative is between 5/1 and 15/1	weight of said micronized fenofibrate in said pharmaceutical composition divided by the weight of binding cellulose derivative as a solubilization adjuvant/agent is between 5 and 15[3]	weight of all of the micronized fenofibrate divided by the weight of all of the binding cellulose derivative is between 5 and 15

[3] Lupin Atlantis and Ethypharm propose this definition with the understanding that it inherently incorporates their proposed construction of the claim terms "micronized fenofibrate" and "binding cellulose derivative as a solubilization adjuvant/agent."

Claim Terms of the '331 Patent To Be Construed By The Court

Claim Term	LAH's/Ethypharm's Proposed Construction	Defendants' Proposed Construction
pharmaceutical composition	LAH and Ethypharm do not believe that any construction is required; however, if deemed necessary, LAH and Ethypharm propose the following: a composition which is suitable for pharmaceutical use	all of the active and inactive ingredients in the final dosage form
the composition	LAH and Ethypharm do not believe that any additional construction is required; however, if deemed necessary, LAH and Ethypharm propose the following: the pharmaceutical composition comprising micronized fenofibrate, a surfactant and hydroxypropylmethylcellulose, wherein said composition is in the form of granules comprising: (a) a neutral core; and (b) an active layer* *the underlined disputed terms are understood to incorporate LAH's/Ethypharm's proposed constructions as outlined below	all of the active and inactive ingredients in the final dosage form
granules	Neutral cores on which there is micronized fenofibrate	many discrete granules

surfactant	A substance that lowers the surface tension of water	**One or more defendants propose the following construction:** a water-soluble substance, that when present in a sufficient amount and under appropriate conditions, increases the bioavailability of fenofibrate, and does not include anti-foaming agents such as simethicone **One or more defendants propose the following construction:** a water-dispersible amphiphilic organic compound that when present in a sufficient amount and under appropriate conditions, reduces the surface tension of water, and does not include anti-foaming agents such as simethicone
hydroxypropylmethylcellulose	A cellulose hydroxypropylmethyl ether that acts to bind the micronized fenofibrate to the neutral core and increases the micronized fenofibrate's solubility and/or rate of solubilization	the total of any and all grades of HPMC in the pharmaceutical composition
neutral core	A pharmaceutically neutral substrate to which active layer can be applied	same as neutral microgranule
active layer	A mixture of micronized fenofibrate, a surfactant, and hydroxypropylmethylcellulose	layer comprised of micronized fenofibrate, surfactant, and binding cellulose derivative sprayed on the outside of the neutral core
sugar	Lactose, mannitol, sucrose or other pharmaceutically acceptable monosaccharide or other lower oligosaccharide	lactose, mannitol, sucrose or other pharmaceutically acceptable monosaccharide or other lower oligosaccharide; not a starch or other polysaccharide

micronized fenofibrate	Fenofibrate that has a smaller particle size than non-micronized fenofibrate such that it exhibits enhanced solubility and/or rate of solubilization when compared to non-micronized fenofibrate	fenofibrate particles of a size less than 15 microns free of other ingredients when micronized, and present in an aqueous suspension with one or more other ingredients when coated on the neutral core or neutral microgranule
wherein the mass ratio of said fenofibrate to said hydroxypropylmethylcellulose is between 5/1 and 15/1	weight of said micronized fenofibrate in the composition divided by the weight of said hydroxypropylmethylcellulose in the composition is between 5 and 15[4]	weight of all of the micronized fenofibrate divided by the weight of all of the hydroxypropylmethylcellulose is between 5 and 15
said hydroxypropylmethylcellulose represents between 5 and 12% by weight of the composition	weight of said hydroxypropylmethylcellulose in the composition divided by the weight of the composition times 100 is between 5 to 12[5]	weight of all of the hydroxypropylmethylcellulose in the pharmaceutical composition divided by the weight of the pharmaceutical composition times 100 is between 5 and 12

Claim Terms Having a Definition To Which the Parties Have Agreed

Claim Term	Agreed Definition
binding cellulose derivative	hydroxypropylmethylcellulose[6]

[4] Lupin Atlantis and Ethypharm propose this definition with the understanding that it inherently incorporates their proposed construction of the claim terms "micronized fenofibrate," "the composition" and "hydroxypropylmethylcellulose."

[5] Lupin Atlantis and Ethypharm propose this definition with the understanding that it inherently incorporates their proposed construction of the claim terms "hydroxypropylmethylcellulose" and "the composition."

[6] To the extent the Court determines this term is capable of construction, Defendants do not propose a different construction. Defendants reserve their right to argue that this term lacks antecedent basis and renders the claim indefinite under 35 U.S.C. 112.

Dated: June 15, 2011

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